

**Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting**

Claims 28-37 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 51 of co-pending Application No. 09/907,931; claims 27-29 of co-pending Application No. 10/858,086; claims 33-42 of U.S. Patent No. 6,398,765; and claim 5 of U.S. Patent No. 6,629,936. Applicants traverse this rejection.

The Examiner states that claims 28-37 are unpatentable over claim 51 of co-pending Application No. 09/907,931 and claims 27-29 of co-pending Application No. 10/858,086. Applicant respectfully disagrees that a terminal disclaimer is appropriate in the instant case. Applicant believes that if and when certain claims of the co-pending applications are found allowable, then the Patent Office should make a decision as to whether or not a terminal disclaimer is warranted. Although the Applicant believes that a terminal disclaimer is not justified, in order to expedite prosecution, the Applicant has filed preliminary amendments cancelling claims 51 of co-pending Application No. 09/907,931 and claims 27-29 co-pending Application No. 10/858,086, thus rendering the rejection moot.

The Examiner states that claims 28-37 are unpatentable over claims 33-42 of U.S. Patent No. 6,398,765 (the '765 patent); and claim 5 of U.S. Patent No. 6,629,936 (the '936 patent). Applicant respectfully disagrees that claims 28-37 are unpatentable over claim 5 of USP 6,629,936. Claim 5 of the '936 patent recites a kit for differentiating between high and low cancer risk comprising a nipple aspiration device and a ductal access tool for obtaining fluid yielded from nipple aspiration. Claims 28-37 of the present invention involve a process know as

ductal lavage. Ductal lavage entails the addition and subsequent removal of fluid through a catheter into a breast duct. The '936 patent describes a process known as nipple aspiration which involves a device which pulls fluid, via vacuum, from a breast duct towards the nipple. The nipple aspirate fluid (NAF) can then be collected by a catheter which is inserted just beyond a ductal orifice in the nipple. There is no washing step involved in this process. Thus, the '936 patent does not teach or suggest a method of ductal lavage. Since the '936 does not teach or suggest the process of ductal lavage, the '936 patent cannot render the claims of the present invention obvious. The Applicant respectfully requests that the obviousness-type double patenting rejection of claims 28-37 in view of claim 5 of U.S. Patent No. 6,629,936 be withdrawn.

The Examiner has also rejected claims 28-37 as being unpatentable over claims 33-42 of U.S. Patent No. 6,398,765 (the '765 patent). A Terminal Disclaimer is being filed concurrently herewith. The Terminal Disclaimer overcomes the outstanding rejection in regards to claims 33-42 of U.S. Patent No. 6,398,765. However, this Terminal Disclaimer is not an admission by the Applicant of the propriety of the double patenting rejection. Reconsideration and withdrawal of the double patenting rejection is respectfully requested.

### **Conclusion**

In light of the arguments presented above, Applicants respectfully submit that the claims 28-37 are in condition for allowance. Early notice to this effect is solicited.

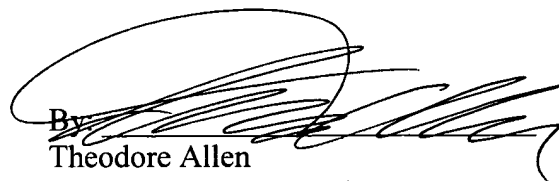
It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of

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this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.025011.

Respectfully submitted,

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